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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/653,730	09/01/2000	Marvin Whiteley	UIZ-038	5801
959	7590	03/09/2004	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			HINES, JANA A	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/653,730	WHITELEY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ja-Na Hines	1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-26 and 75-82 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 75-76 is/are allowed.
- 6) ☒ Claim(s) 3-26 and 77-82 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 12, 2003 has been entered.

### **Amendment Entry**

2. The amendment filed December 12, 2003 has been entered. Claims 1, 3, 7, 9, 13, 17, 21 24, 25 and 26 have been amended. Claims 76-82 have been newly added. Claims 1, 3-26 and 75-82 are under consideration.

### ***Withdrawal of Rejections***

3. The following rejections have been withdrawn:
- a) The objection of claims 3, 7, 9, 17, 21 24, 25 and 26;
  - b) The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Pearson et al., (J. of Bacterio. 1997. 179(18): 5756-5767);

***Response to Arguments***

4. Applicant's arguments filed December 12, 2003 have been fully considered but they are not persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. The rejection of claims 3-7, 9-10, 13-15, 17-26 and 77 under 35 U.S.C. 102(b) as being anticipated by Pearson et al., (J. of Bacterio. 1997. 179(18): 5756-5767) is maintained for reasons already of record. The rejection was on the grounds that Pearson et al., teach a method for identifying a modulator of quorum sensing signaling in bacteria, comprising the claimed steps.

Applicants assert that Pearson et al., does not teach that the test compound is other than the quorum sensing signal molecule. In response to applicant's argument that the Pearson et al., reference fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the test compound is other than the quorum sensing signal molecule) is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). It is noted that new independent claim 77 does not require that the test compound is other than the quorum sensing signal molecule. Claims 3-7, 9-10, 13-15, 17-26 and 77 are all recite alternative language to embrace claim 77. Therefore, applicants' arguments are not found persuasive.

In response to applicant's arguments that Pearson et al., does not teach an assay to identify a modulator of quorum sensing signaling, the recitation of a method to identify a modulator of quorum sensing signaling has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Moreover, at page 5762 the authors conclude that PAI-2 is a modulator of quorum sensing signaling in bacteria (page 5762). Therefore, Pearson et al., teach a method to identify modulators.

It is also noted that that the claims only requires a cell which is capable of endogenously synthesizing a quorum sensing signal, therefore, the cell does not have to actually synthesize a quorum sensing signal. Furthermore, Pearson et al., teach several cells which would be capable of endogenously producing a quorum sensing signal.

6. The rejection of claims 8, 11-12 and 16 under 35 U.S.C. 103(a) as being unpatentable over Pearson et al., (J. of Bacterio. 1997. 179(18): 5756-5767) in view of Passador et al., (Science, 1993. 260:1127-1130) is maintained for reasons already of record. The rejection was on the grounds that it would have been prima facie obvious at the time of applicants invention to modify the method for identifying a modulator of quorum sensing signaling in bacteria comprising the recited steps as taught by Pearson et al., to include a second cell that produces the quorum sensing signal molecule, instead of adding the molecule to the cell.

Applicants assert that the contact step wherein the cell is contacted in the presence and absence of the test compound distinguishes the claims from the prior art. However, Pearson et al., teach controls which thereby meet the limitations of the claims with regard to the contact step.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one would have a reasonable expectation of success in using a second cell to produce the molecule since Passador et al., teach that the expression of *P. aeruginosa* virulence genes requires cell-to-cell communication whereby one cell produces the molecule and the

other cell can respond to the production of the molecule. No more than routine skill would have been required to incorporate a second cell which is a wild type *P.aeruginosa* cell that express one of the virulence factors, using cells constructed in a similar manner as the cells of Pearson et al., which allows detection of a change to identify a compound as a modulator of quorum sensing signaling in bacteria. Therefore, applicants' arguments are not persuasive.

### ***New Grounds of Rejection***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 5-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The acronyms in the claims must be spelled out when used for the first time in a chain of claims.


#### ***Allowable Subject Matter***

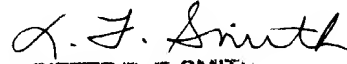
8. Claims 1 and 75-76 are allowable.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines   
February 25, 2004

  
LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER